



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Dorothy B. Franks et al.

Serial No.: 09/620,520

Filed: July 20, 2000

For: AUTOMATIC
IDENTIFICATION OF
MEDICAL STAFF TRAINING
NEEDS

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Group Art Unit: 3714

Examiner: Sotomayor, John

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APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 1.191 AND 1.192

This Appeal Brief is being filed in furtherance to the Notice of Appeal mailed on August 4, 2003, and received by the Patent Office on August 14, 2003.

As discussed in detail below, the Appellants believe the Examiner has expended unnecessary time and resources, both of the Patent Office and Appellants, with unreasonable rejections and incomplete readings of the prior art and the present claims. In particular, the Examiner's repeated obviousness rejections under Section 103 clearly ignore certain features recited in the present claims. A *prima facie* case of obviousness requires consideration of each and every claim recitation in context of the claim as a whole. See *In re Wilson*, 424 F.2d 1382, 1385 (C.C.P.A. 1970); M.P.E.P. § 2143.03. Moreover, the Appellants emphasize the Examiner's failure to interpret the claims in a reasonable manner, which is consistent with regard to the scope of the present application and with regard to the interpretation that those of ordinary skill in the art would reach. See *In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); see also *In re Morris*, 127 F.3d 1048, 1054-55, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); see also *In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); see also M.P.E.P. §§ 608.01(o) and 2111.

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The present application discloses a system for *identifying a training need* based on an *analysis* of various data, such as *equipment operation data*, which is associated with biomedical equipment components. In contrast, the primary reference, i.e., Callahan (U.S. Patent No. 6,416,328), focuses on *process* management (i.e., human task management) and the distribution of *existing* training materials to complete those processes (i.e., predefined processes and government regulations). See Callahan, col. 1, lines 10-16; col. 4, lines 21-27; col. 5, lines 60-63; col. 6, lines 8-10, 24-37, and 62-67; col. 7, lines 47-52; col. 8, lines 15-25 and 37-40. Although Callahan monitors *human* progress of *processes*, the reference does not teach or suggest any analysis of data associated with *equipment*, much less an identification of training *needs* based on those analyses. The secondary reference, i.e., Linberg et al. (U.S. Patent No. 6,497,655), also fails to disclose identification of training needs based on data analysis, as recited in each independent claim 1, 15, 23, and 28. The Examiner's interpretation of the present claims and the cited references is clearly unreasonable and inconsistent with the scope of the present application and the interpretation that those of ordinary skill in the art would reach the.

For these reasons, as set forth in further detail below, Appellants respectfully request that the Board find claims 1-28 patentable over the prior art of record and withdraw all outstanding rejections.

1. **REAL PARTY IN INTEREST**

The real party in interest is GE Medical Technology Services, Inc., the Assignee of the above-referenced application by virtue of the Assignment recorded at reel 011193, frame 0029, and recorded on October 16, 2000. GE Medical Technology Services, Inc., the Assignee of the above-referenced application, as evidenced by the documents mentioned above, will be directly affected by the Board's decision in the pending appeal.

2. **RELATED APPEALS AND INTERFERENCES**

Appellants are unaware of any other appeals or interferences related to this Appeal. The undersigned is Appellants' legal representative in this Appeal.

3. **STATUS OF CLAIMS**

Claims 1-28 are currently pending, and claims 1-28 are currently under final rejection and, thus, are the subject of this appeal.

4. **STATUS OF AMENDMENTS**

The Appellant has not submitted any amendments subsequent to the Final Office Action mailed on June 3, 2003.

5. **SUMMARY OF THE INVENTION AND OF THE DISCLOSED EMBODIMENTS**

In medical facilities, the need for training is particularly apparent due to the widerange of existing biomedical equipment systems and due to the continual, and sometimes rapid, evolution of these biomedical equipment systems. *See Application*, page 1, lines 13-23. Typically, personnel utilize *existing* training mechanisms at *predefined* times. For example, personnel generally receive training at the time of initial employment, at the time of purchasing new biomedical equipment systems, and at conferences. *See Application*, page 1, lines 25-29. Personnel also may review various texts, journals, and other readily available materials. *See id.* Unfortunately, these techniques do not adequately address specific training needs of clients and their use of biomedical equipment systems. *See Application*, page 1, line 29 - page 2, line 4. One major problem associated with these training techniques is the *lack of any feedback* to ensure the appropriate time, amount, focus, and type of training materials. *See Application*, page 2, line 1 - page 3, line 9. Without such feedback, the training techniques may be untimely, insufficient, misdirected, and improper for the particular equipment, personnel, and scenario. As a consequence, the medical diagnosis and treatment provided by personnel operating the biomedical equipment systems can result in patient mistreatment and harm, equipment damage, and generally poor utilization of biomedical equipment systems.

The present application targets the drawbacks of conventional training techniques by monitoring, collecting, logically grouping, analyzing, and reporting data relating to biomedical equipment and one or more medical institutions. *See Application*, page 4, lines 15-17; page 7, lines 17-23; page 8, lines 19-28. For example, the data may comprise equipment data (e.g., inventory, operational history, performance, etc.), service data (e.g., service contracts, warranties, service history, etc.), and personnel data. *See Application*, page 4, lines 22-25; page 8, line 22 - page 9, line 7; page 14, line 8-11 and 28-31; page 15, lines 7-11. It is important to point out that the present application is not a mere data monitoring and collection technique, but rather the disclosed system 10 actively and logically groups, processes, and analytically generates results targeting equipment performance and training *needs* of personnel. *See Application*, page 9, lines 9-28; page 10, lines 23-31; page 12, lines 19-26; page 13, lines 2-6 and 11-16; page 14, line 28 - page 15, line 11. Moreover, the disclosed system 10 does not merely distribute preexisting training materials, but rather the system 10 analyzes the acquired data to provide *feedback-*

based control of personnel training for the biomedical equipment systems. *See Application*, page 3, lines 2-9; page 14, line 28 - page 15, line 11. As a result, the system 10 actively improves training techniques to enhance the overall performance and use of the biomedical equipment systems. *See id.*

6. **ISSUES**

Issue No. 1:

Whether claims 1, 8-10, 23, and 28 are unpatentable under 35 U.S.C. 103(a) as obvious over Callahan (U.S. Pat. No. 6,416,328).

Issue No. 2:

Whether claims 2-7, 11-22, and 24-27 are unpatentable under 35 U.S.C. 103(a) as obvious over Callahan in view of Linberg et al. (U.S. Pat. No. 6,497,655).

7. **GROUPING OF CLAIMS**

- Group I: Independent claim 1 and dependent claims 2-14 will stand or fall together.
Group II: Independent claim 15 and dependent claims 16-22 will stand or fall together.
Group III: Independent claim 23 and dependent claims 24-27 will stand or fall together.
Group IV: Independent claim 28 will stand or fall alone.

8. **ARGUMENT**

Issue No. 1:

In the Final Office Action, the Examiner rejected independent claims 1, 8-10, 23, and 28 under 35 U.S.C. 103(a) as obvious over Callahan (U.S. Pat. No. 6,416,328). Appellants traverse these rejections and request the Board withdraw the outstanding rejections for the reasons set forth below the following legal precedent.

First, regarding claim interpretation, the claims must be given their broadest reasonable interpretation consistent with the specification. *See In re Prater*, 415 F.2d 1393, 1404-05, 162 U.S.P.Q. 541, 550-51 (C.C.P.A. 1969); *see also In re Morris*, 127 F.3d 1048, 1054-55, 44 U.S.P.Q.2d 1023, 1027-28 (Fed. Cir. 1997); *see also* M.P.E.P. §§ 608.01(o) and 2111. Interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *See In re Cortright*, 165 F.3d 1353, 1359, 49 U.S.P.Q.2d 1464, 1468 (Fed. Cir. 1999); *see also* M.P.E.P. § 2111. As further explained

in Section 2111.01 of the M.P.E.P., the words of the claim must be given their plain meaning unless the applicant has provided a clear definition in the specification. *See In re Zletz*, 893 F.2d 319, 321, 13 U.S.P.Q.2d 1320, 1322 (Fed. Cir. 1989). Again, the plain meaning refers to an interpretation by those of ordinary skill in the art. *See In re Sneed*, 710 F.2d 1544, 218 U.S.P.Q. 385 (Fed. Cir. 1983).

Second, regarding obviousness, the burden of establishing a *prima facie* case of obviousness falls on the Examiner. *Ex parte Wolters and Kuypers*, 214 U.S.P.Q. 735 (PTO Bd. App. 1979). The Examiner must provide objective evidence, rather than subjective belief and unknown authority, of the requisite motivation or suggestion to combine or modify the cited references. *In re Lee*, 61 U.S.P.Q.2d. 1430 (Fed. Cir. 2002). Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching or suggestion supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 U.S.P.Q. 929, 933 (Fed. Cir. 1984). Accordingly, to establish a *prima facie* case, the Examiner must not only show that the combination includes *all* of the claimed elements, but also a convincing line of reason as to why one of ordinary skill in the art would have found the claimed invention to have been obvious in light of the teachings of the references. *Ex parte Clapp*, 227 U.S.P.Q. 972 (B.P.A.I. 1985). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d. 1430 (Fed. Cir. 1990). Moreover, a statement that the proposed modification would have been “well within the ordinary skill of the art” based on individual knowledge of the claimed elements cannot be relied upon to establish a *prima facie* case of obviousness without some *objective reason to combine* the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993); *In re Kotzab*, 217 F.3d 1365, 1371, 55 U.S.P.Q.2d. 1313, 1318 (Fed. Cir. 2000); *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 50 U.S.P.Q.2d. 1161 (Fed. Cir. 1999). When prior art references require a selected combination to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gained from the invention itself, i.e., something in the prior art as a whole must suggest the desirability, and thus the obviousness, of making the combination. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988). One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Third, it is improper to combine references where the references teach away from their combination. *In re Grasselli*, 713 F.2d 731, 743, 218 U.S.P.Q. 769, 779 (Fed. Cir. 1983); M.P.E.P. §

2145. Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959); see M.P.E.P. § 2143.01.

Fourth, regarding the theory of inherency, the extrinsic evidence must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999) (Emphasis Added). The mere fact that a certain thing *may* result from a given set of circumstances is not sufficient. *Id.* In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Examiner, in presenting the inherency argument, bears the evidentiary burden and must adequately satisfy this burden. *See id.* Regarding functional limitations, the Examiner must evaluate and consider the functional limitation, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. *See* M.P.E.P. § 2173.05(g); *In re Swinehart*, 169 U.S.P.Q. 226, 229 (C.C.P.A. 1971); *In re Schreiber*, 44 U.S.P.Q.2d 1429, 1432 (Fed. Cir. 1997). If the Examiner believes the functional limitation to be inherent in the cited reference, then the Examiner “must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art.” *Ex parte Skinner*, 2 U.S.P.Q.2d 1788, 1789 (Bd. Pat. App. & Inter. 1986).

GROUP I: Independent Claim 1 and Dependent Claims 2-14

The Examiner rejected independent claim 1 and dependent claims 8-10 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 1 recites:

A method of identifying training needs for biomedical equipment in a medical facility, the method comprising:
collecting identification and operation data associated with a plurality of biomedical equipment components;
storing the collected data in a central database;
analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and

identifying a training need based on the analyzed operational parameter.

As set forth above, claim 1 is clearly directed toward *need*-based training, which is identified according to *analyzed* data associated with *equipment*. In this manner, the act of “identifying a training need” is not a mere identification of *existing* training material, but rather it is associated with *needs* that are discernible by means of the foregoin data feedback and data analysis.

As mentioned above, the Examiner clearly *ignored or mischaracterized* certain features of the present claims in formulating the foregoing rejections. Some of the recited features of claim 1 that are not disclosed by the Callahan reference are: “collecting identification and *operation* data associated with a plurality of biomedical *equipment* components,” “*analyzing* the operation data to identify at least one operational parameter *affected by operator activities* with the equipment components,” and “identifying a training *need* based on the analyzed operational parameter.”

A prima facie case obviousness requires that *all* the claim limitations be taught or suggested by the prior art. *In re Royka*, 180 U.S.P.Q. 580 (C.C.P.A. 1974); *see also* M.P.E.P. § 2143.03. “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970). Moreover, if an independent claim is nonobvious under 35 U.S.C. § 103 then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Turning to the cited reference, Callahan is directed to a *process* management system for handling *human* task and training associated with those human tasks. Callahan, col. 1, line 64 to col. 2, line 11. The reference further discloses that the Federal Government requires healthcare providers to be in compliance with certain predefined *procedures and regulations*. Callahan, col. 1, lines 24-44. By their very nature, these *predefined* procedures and regulations are beyond control of the healthcare providers. Accordingly, the healthcare providers must follow these procedures and regulations to the letter. Accordingly, Callahan discloses a system that includes a process management means 12 for maintaining a listing of processes that must be performed to maintain compliance with these predefined procedures and regulations. Callahan, col. 2, lines 21-27. This system also includes a training means 16 for tracking employee training, classifying employees positions, and coordinating the desired training. Callahan, col. 5, line 60 to col. 6, line 2. A training coordinating means 22 determines the training for an employee from the training that they have received, employee position, and the requirements of the position. Callahan, col. 6, lines 24-34. The system

may even include a contractor management means 20 for managing the contractors to ensure that they are in compliance with required processes. Callahan, col. 7, lines 39-52. Again, all of these procedures and training requirements are *predefined*.

The Callahan reference does not disclose *collecting operation data*, *analyzing the operation data*, and *identifying a training need based on the analyzed operational parameter*. Rather, the portion of the Callahan reference cited by the Examiner simply describes the tracking and coordinating of the *predetermined* training requirements for an employee *based on a predetermined process*, not based upon collected operation data. In addition, the Examiner cited a portion of the reference that merely discloses managing timing and distribution of the training materials for contractors. The Callahan reference does not disclose *collecting operation data* as a basis for identifying training requirements for a particular human task. Moreover, the reference is devoid of any reference to *biomedical equipment* or even the data associated with *biomedical equipment*. Accordingly, the reference cannot disclose or suggest “collecting identification and operation data associated with a plurality of biomedical equipment components,” as recited in independent claim 1.

Further, the Callahan reference does not disclose *analyzing the operation data*. In fact, Callahan simply stores, tracks, and distributes predefined human tasks/procedures and predefined training materials for those tasks/procedures. Callahan, column 4, lines 21-27 and 37-41. For example, means for storing data 16 retains a variety of *predefined* data, yet this data is not associated with equipment and it is not subject to any analysis. Callahan, column 5, lines 20-30. Instead, Callahan simply implements *existing* regulations and procedures that are stored on the data storing means 16 (i.e., provides training *independent* of any consideration of actual operational data). Additionally, as the reference is devoid of any reference to *biomedical equipment*, the Callahan reference fails to disclose *analyzing the operation data*. Accordingly, the reference cannot disclose or suggest “analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components,” as recited in independent claim 1.

Moreover, the Callahan reference does not disclose *identifying a training need based on the analyzed operational parameter*. The Callahan reference discloses determining training requirements based on predefined procedures and regulations received and placed into the storage means 14. Callahan, col. 7, lines 31-37. However, *predefined procedures and regulations* should not be confused with *needs* that are identified based on analyzed data, as set forth in independent claim 1. In the rejection, the Examiner asserted

that the operational parameters may be developed to solve the training needs of maintenance or janitorial crews. However, the reference actually discloses the contractors, such as maintenance, janitorial crews, or doctors, as being one of the groups that is to be trained because the contractors perform procedures for the provider. Callahan, col. 1, lines 46-48; col. 7, lines 39-46. These groups are included because the provider is ultimately responsible for the compliance with the predefined procedures and regulations. Callahan, col. 1, lines 36-48. As such, the passage only means that contractors may be trained on the predefined procedures and regulations in addition to the other employees, which helps to maintain the compliance with the regulations. In addition, a person of ordinary skill in the art would not know how to plan or identify training *needs* by reading the Callahan reference, and certainly would not be led to *analyze* operational parameters for that purpose. The reference only discloses that the training needs result from new procedures, not from analyzed operational parameters. Accordingly, the reference fails to disclose or suggest “identifying a training need based on the analyzed operational parameter,” as recited in independent claim 1.

Because the Callahan reference does not disclose or suggest *all* of the recited features, the Examiner has failed to establish that Callahan renders the claimed subject matter obvious. Therefore, independent claim 1 and its respective dependent claims are believed to be patentable over the Callahan reference.

GROUP III: Independent Claim 23 and Dependent Claims 24-27

The Examiner rejected independent claim 23 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 23 recites:

A method for identifying a training need associated with biomedical equipment in a medical institution, the method comprising:
storing data associated with the equipment in a central database, the stored data including equipment operation data and equipment identification data;
logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data;
analyzing the equipment operation data based on the logical grouping;
generating a presentation of the analyzed equipment operation data in accordance with the logical grouping; and
identifying a training need associated with a particular piece of equipment based on the presentation.

As set forth above, claim 23 is clearly directed toward *need*-based training, which is identified according to *analyzed* data associated with *equipment*. In this manner, the act of “identifying a training need” is not a

mere identification of *existing* training material, but rather it is associated with *needs* that are discernible by means of the recited data feedback and data analysis.

As mentioned above, the Examiner clearly *ignored or mischaracterized* certain features of the present claims in formulating the foregoing rejections. Some of the recited features of claim 23 that are not disclosed by the Callahan reference are: “logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data,” “analyzing the equipment operation data based on the logical grouping,” and “identifying a training need associated with a particular piece of equipment based on the presentation.”

Again, the Callahan reference fails to disclose *equipment operation data*, and is devoid of any reference to *biomedical equipment* or even the data associated with *biomedical equipment*. Moreover, Callahan is absolutely devoid of any sort of grouping, much less logical grouping, of data within the data storage means 16. Logical grouping does not necessarily flow from a disclosure of mere storage of data. Moreover, such logical grouping would be irrelevant to the system of Callahan, which is focused on mere storage and distribution of the data, i.e., predefined procedures and predefined training requirements. Accordingly, the reference cannot disclose or suggest “logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data,” as recited in independent claim 23.

The Callahan reference also does not disclose *analyzing the equipment operation data*. Additional training for employees is determined based on the receipt of new predefined procedures and regulations. Callahan, col. 1, lines 46-48; col. 7, lines 39-46. Moreover, as the reference is devoid of any reference to *biomedical equipment*, the Callahan reference cannot disclose *analyzing the equipment operation data*. Accordingly, the reference cannot disclose or suggest “analyzing the equipment operation data based on the logical grouping,” as recited in independent claim 23.

Moreover, the Callahan reference does not disclose *identifying a training need associated with a particular piece of equipment*. As discussed previously, the Callahan reference discloses determining training requirements based on *predefined* procedures or regulations, not based on *analyzed equipment operational data in a presentation*. Callahan, col. 7, lines 31-37. Again, the reference is devoid of any reference to biomedical equipment and merely mentions maintenance and janitorial crews as part of a contractor group that may be performing procedures for the provider. Further, the Callahan reference only

discloses that the training requirements result from new procedures, not from *analyzed equipment operational data in a presentation*. Thus, the reference would not enable a person of ordinary skill in the art to identify training needs associated with a particular piece of equipment. Accordingly, the reference fails to disclose or suggest “identifying a training need associated with a particular piece of equipment based on the presentation,” as recited in the claim.

Because the Callahan reference does not disclose or suggest *all* of the recited features, the Examiner has failed to establish that Callahan renders the claimed subject matter obvious. Therefore, independent claim 23 and its respective dependent claims are believed to be patentable over the Callahan reference.

GROUP IV: Claim 28

The Examiner rejected independent claim 28 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328). Claim 28 recites:

A system for of identifying training needs for biomedical equipment in a medical facility, the method comprising:
 means for collecting identification and operation data associated with a plurality of biomedical equipment components;
 means for storing the collected data in a central database;
 means for analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and
 means for identifying a training need based on the analyzed operational parameter.

Again, claim 28 is clearly directed toward *need*-based training, which is identified according to *analyzed* data associated with *equipment*. In this manner, the act of “identifying a training need” is not a mere identification of *existing* training material, but rather it is associated with *needs* that are discernible by means of the recited data feedback and data analysis.

As mentioned above, the Examiner clearly *ignored or mischaracterized* certain features of the present claims in formulating the foregoing rejections. Some of the recited features of claim 28 that are not disclosed by the Callahan reference are: “means for *collecting* identification and operation data associated with a plurality of biomedical *equipment* components,” “means for *analyzing* the operation data to identify at least one *operational parameter affected by operator activities* with the equipment components,” and “means for *identifying a training need* based on the analyzed operational parameter.”

As discussed in detail above, Callahan is directed to a *process* management system for handling *human* task and training associated with those human tasks. Callahan, col. 1, line 64 to col. 2, line 11. Callahan further discloses a system employing a process management means 12 for maintaining a listing of processes that must be performed to maintain compliance with predefined procedures and regulations. Callahan, col. 2, lines 21-27. This system also includes a training means 16 for tracking employee training, classifying employees positions, and coordinating the desired training. Callahan, col. 5, line 60 to col. 6, line 2. Again, all of these procedures and training requirements are predefined.

The Callahan reference does not disclose *means for collecting identification and operation data*, *means for analyzing the operation data*, and *means for identifying a training need based on the analyzed operational parameter*. Instead, the Callahan reference simply describes the tracking and coordinating of the *predetermined* training requirements for an employee *based on a predetermined process*, not based upon collected operation data. The Callahan reference does not disclose *collecting operation data* as a basis for identifying training requirements for a particular human task. Moreover, the reference is devoid of any reference to *biomedical equipment* or even the data associated with *biomedical equipment*. Accordingly, the reference cannot disclose or suggest “means for collecting identification and operation data associated with a plurality of biomedical equipment components,” as recited in independent claim 28.

Further, the Callahan reference does not disclose *means for analyzing the operation data*. In fact, Callahan simply stores, tracks, and distributes predefined human tasks/procedures and predefined training materials for those tasks/procedures. Callahan, column 4, lines 21-27 and 37-41. For example, means for storing data 16 retains a variety of *predefined* data, yet this data is not associated with equipment and it is not subject to any analysis. Callahan, column 5, lines 20-30. Instead, Callahan simply implements *existing* regulations and procedures that are stored on the data storing means 16 (i.e., provides training *independent* of any consideration of actual operational data). Additionally, as the reference is devoid of any reference to *biomedical equipment*, the Callahan reference fails to disclose *analyzing the operation data*. Accordingly, the reference cannot disclose or suggest “means for analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components,” as recited in independent claim 28.

Moreover, the Callahan reference does not disclose *means for identifying a training need based on the analyzed operational parameter*. The Callahan reference discloses determining training requirements

based on predefined procedures and regulations received and placed into the storage means 14. Callahan, col. 7, lines 31-37. However, *predefined procedures and regulations* should not be confused with *needs* that are identified based on analyzed data, as set forth in independent claim 28. As discussed above, a person of ordinary skill in the art would not know how to plan or identify training *needs* by reading the Callahan reference, and certainly would not be led to *analyze* operational parameters for that purpose. The reference only discloses that the training requirements result from new predefined procedures and regulations, not from analyzed operational parameters. Accordingly, the reference fails to disclose or suggest “means for identifying a training need based on the analyzed operational parameter,” as recited in independent claim 28.

Because the Callahan reference does not disclose or suggest *all* of the recited features, the Examiner has failed to establish that Callahan renders the claimed subject matter obvious. Therefore, independent claim 28 is believed to be patentable over the Callahan reference.

Issue No. 2:

In the Final Office Action, the Examiner rejected claims 2-7, 11-22, and 24-27 under 35 U.S.C. 103(a) as obvious over Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655). Appellants traverse these rejections and request the Board withdraw the outstanding rejections for the reasons set forth below.

GROUP II: Independent Claim 15 and Dependent Claims 16-22

The Examiner rejected claims 15-22 under 35 U.S.C. 103(a) as obvious over Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655).

Regarding independent claim 15, this claim recites:

A system for identifying training needs associated with a plurality of biomedical equipment components in a medical institution, the system comprising:

a central database configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type;

a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping; and

a report generator configured to generate a report including an arrangement of the analyzed operation data based on the logical

groupings, wherein a training need is identifiable based on the arrangement.

Again, claim 15 is clearly directed toward *need*-based training, which is identified according to *analyzed* and *logically grouped* data associated with *equipment*. In this manner, the act of “identifying a training need” is not a mere identification of *existing* training material, but rather it is associated with *needs* that are discernible by means of the recited data feedback, data analysis, and logical groupings.

As mentioned above, the Examiner clearly *ignored or mischaracterized* certain features of the present claims in formulating the foregoing rejections. Some of the recited features of claim 15 that are not disclosed by the Callahan reference are: “a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping” and “wherein a training need is identifiable based on the arrangement.” As the reference fails to disclose or suggest all of the recited features, the rejection cannot stand. In addition, the Examiner has provided no sufficient suggestion or motivation to combine these references.

Further, the Callahan reference does not disclose a data analysis module, much less arranging the operation data into logical groupings or analyzing the operation data based on the logical groupings. In fact, Callahan simply stores, tracks, and distributes predefined human tasks/procedures and predefined training materials for those tasks/procedures. Callahan, column 4, lines 21-27 and 37-41. For example, means for storing data 16 retains a variety of *predefined* data, yet this data is not associated with equipment and it is not subject to any analysis. Callahan, column 5, lines 20-30. Instead, Callahan simply implements *existing* regulations and procedures that are stored on the data storing means 16 (i.e., provides training *independent* of any consideration of actual operational data). Additionally, as the reference is devoid of any reference to *biomedical equipment*, the Callahan reference fails to disclose *a data analysis module data*. Accordingly, the reference cannot disclose or suggest “a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings” as recited in independent claim 15.

Moreover, the Callahan reference does not disclose that *a training need is identifiable based on the arrangement* of analyzed operation data based on logical groupings. The Callahan reference discloses determining training requirements based on predefined procedures and regulations received and placed into the storage means 14. Callahan, col. 7, lines 31-37. However, *predefined procedures and regulations* should

not be confused with *needs* that are identified based on an arrangement of analyzed operation data based on logical groupings, as set forth in independent claim 15. As discussed above, a person of ordinary skill in the art would not know how to plan or identify training *needs* by reading the Callahan reference, and certainly would not be led to *analyze* or *logically group* data for that purpose. The reference only discloses that the training requirements result from new predefined procedures and regulations, not from analyzed or logically grouped data. Accordingly, the reference fails to disclose or suggest “a report generator configured to generate a report including an arrangement of the analyzed operation data based on the logical groupings, wherein a training need is identifiable based on the arrangement,” as recited in independent claim 15.

The secondary reference, i.e., Linberg et al., also fails to obviate the deficiencies of the primary reference. The Linberg et al. reference is directed to a communication scheme for a remote web-based data center that interacts with a patient having a implantable medical device (IMD). Linberg et al., col. 8, lines 23-27. The reference further discloses that the IMD is remotely monitored for upgrades or debugging of the system. Linberg et al., col. 8, lines 44-63. The IMD 10 is a microprocessor-based system that provides sensing functions for a patient, such as patient health monitoring. Linberg et al., col. 10, lines 53-66. The IMD 10 communicates patient data to a remote data center 62 to assist in the patient diagnosis. Linberg et al., col. 12, lines 21-47.

In the Office Action, the Examiner cited the Linberg et al. reference only for its alleged teaching of operational data that is collected by *equipment* type. However, the portion of the Linberg reference cited by the Examiner simply discloses using operational parameters to upgrade, fine tune, or adjust the implantable medical devices. Nothing in the cited passage discloses or teaches *arranging* or *analyzing the logical groupings of operation data* or *logical groupings that include equipment type groupings*. Accordingly, the references fail to teach or suggest, taken alone or in combination, “a data analysis module configured to arrange the operation data into *logical groupings* and to analyze the operation data based on the logical groupings, the logical groupings including an *equipment type grouping*,” as recited in independent claim 15.

Moreover, assuming, *arguendo*, such combination of Callahan and the Linberg et al. were even possible, the Examiner has failed to point to a convincing suggestion or motivation that would lead one skilled in the art to modify the Callahan system or the Linberg et al. system as proposed. Indeed, the Examiner merely stated:

The motivation to combine these two references lies in the desire of equipment manufacturers to provide training services to clients who purchase their equipment and in the clients identified need for training based upon operational data collected within the facility that shows a training need among maintenance and janitorial crews, and doctors. Combining the system disclosed by Callahan with the teaching of Linberg et al produces a system whereby greater communication is fostered between suppliers and purchasers of health related equipment, including biomedical equipment, to alleviate training deficits among staff users of the identified equipment.

Paper 4, Page 5. As discussed in detail above, a *prima facie* case of obviousness requires objective evidence of the requisite motivation or suggestion to combine the references. Mere conclusory statements are insufficient, particularly where such statements appear to be a regurgitation of the present application. Indeed, the Examiner has impermissibly relied on hindsight, using the teachings of Appellants to find the suggestion to combine the alleged teachings of Callahan and Linberg et al.

In particular, the Callahan reference is directed to a control system for handling task management and training. Indeed, the Callahan reference is strictly related to a process of monitoring and tracking training of predefined regulations and procedures, and is devoid of any reference to biomedical equipment. Conversely, the Linberg et al. reference is directed to a communication scheme for a remote web-based data center that interacts with a patient having a implantable medical device (IMD).

The Examiner asserted that the motivation to combine the references lies in the desire of equipment manufacturers to provide training services. However, as discussed in detail above, Callahan does not teach or suggest any identification of training *needs* but rather the reference is limited to *predefined* procedures and regulations and the corresponding training requirements to carry out those procedures and regulations. Callahan, col. 1, lines, lines 24-44. Thus, Callahan merely discloses the storage and distribution of such procedures and training requirements without any reference to *needs* and without any correlation to *equipment*. Conversely, the Linberg et al. reference is directed to a communication scheme for a data center and an implantable medical device (IMD). Linberg does not disclose or teach identifying training *needs* associated with the IMD. Accordingly, a person of ordinary skill in the art would not know how to plan or identify training needs by reading the Linberg et al. reference in view of the Callahan reference.

Accordingly, because the Examiner has failed to show that the cited references disclose *all* of the claimed elements, as well as a convincing line of reasoning as to why one of ordinary skill in the art would have found the claimed invention obvious in light of the cited reference, the Examiner has failed to establish a *prima facie* case of obviousness. Therefore, independent claim 15 and its dependent claims are believed to be patentable over Callahan in view of Linberg et al.

GROUP I: Dependent Claims 2-7 and 11-14

The Examiner rejected dependent claims 2-7 and 11-14 under 35 U.S.C. 103(a) as rendered obvious by Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655).

Appellants believe claims 2-7 and 11-14 are patentable based upon both their dependence on patentable claim 1, and their recited subject matter. As discussed above, the Callahan and Linberg et al. references fail to disclose all of the recited features of independent claim 1. As the Linberg et al. reference fails to cure the deficiencies of Callahan, the references cannot render the claimed subject matter obvious. Accordingly, Appellants respectfully request withdrawal of the Examiner's rejection and allowance of the dependent claims 2-7 and 11-14.

Group III: Dependent Claims 24-27

The Examiner rejected dependent claims 24-27 under 35 U.S.C. 103(a) as being rendered obvious by Callahan (U.S. Pat. No. 6,416,328) in view of Linberg et al. (U.S. Pat. No. 6,497,655).

Again, Appellants believe claims 24-27 are patentable based upon both their dependence on independent claim 23, and their recited subject matter. As discussed above, the Callahan and Linberg et al. references fail to disclose the all of the recited features of claim 23. As the Linberg et al. reference fails to cure the deficiencies of Callahan, the references cannot render the claimed subject matter obvious. Accordingly, Appellants respectfully request withdrawal of the Examiner's rejection and allowance of the dependent claims 24-27.

9. **CONCLUSION**

In view of the above remarks, Appellants respectfully submit that the Examiner has provided no supportable position or evidence that claims 1-28 are obvious under 35 U.S.C. § 103. Accordingly,

Appellant respectfully requests that the Board find claims 1-28 patentable over the prior art of record and withdraw all outstanding rejections.

Fees and General Authorization for Extensions of Time

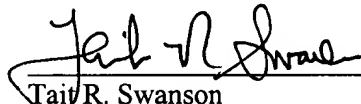
The Commissioner is authorized to charge the requisite fee of \$330.00, and any additional fees which may be required, to Account No. 50-2402, Order No. 15-SV-5495/YOD (GEMS:0091).

Appellants hereby request a one (1) month extension in the statutory period for response from October 14, 2003 to November 14, 2003 in accordance with 37 C.F.R. § 1.136. The Commissioner is authorized to charge the requisite fee of \$110.00, and any additional fees which may be required, to Deposit Account No. 50-2402, Order No. 15-SV-5495/YOD (GEMS:0091).

In accordance with 37 C.F.R. § 1.136, Appellants hereby provide a general authorization to treat this and any future reply requiring an extension of time as incorporating a request therefor. Furthermore, Appellants authorize the Commissioner to charge the appropriate fee for any extension of time to Deposit Account No. 50-2402, Order No. 15-SV-5495/YOD (GEMS:0091).

Respectfully submitted,

Date: November 14, 2003



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10. **APPENDIX OF CLAIMS ON APPEAL**

1. A method of identifying training needs for biomedical equipment in a medical facility, the method comprising:
 - collecting identification and operation data associated with a plurality of biomedical equipment components;
 - storing the collected data in a central database;
 - analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and
 - identifying a training need based on the analyzed operational parameter.
2. The method of claim 1, wherein the operational parameter includes operational errors for a type of equipment component.
3. The method of claim 1, wherein the operational parameter includes failures for a type of equipment component.
4. The method of claim 1, wherein the data includes equipment type, and wherein the training need is identified by analyzing the operational parameter for a plurality of equipment components of the equipment type.
5. The method of claim 1, wherein the data includes data representative of individual operators utilizing the equipment components.
6. The method of claim 1, wherein the medical institution includes a plurality of departments, and wherein the data includes data representative of the department to which equipment components are assigned.
7. The method of claim 1, wherein the medical institution includes a plurality of geographically dispersed facility sites, and wherein the data includes data representative of the facility site at which equipment components are located.

8. The method of claim 1, comprising the further step of generating a report of training need identified.

9. The method of claim 8, wherein the report is generated at a location remote from the medical institution and is transmitted to the medical institution by a configurable network link.

10. The method of claim 9, wherein the network link includes the Internet.

11. The method of claim 1, comprising the further step of associating the stored data into logical groups by equipment type, and wherein the training need is identified for an equipment type group.

12. The method of claim 11, further comprising associating the stored data into logical groups by equipment location, wherein the training need is identified for an equipment type group and an equipment location group.

13. The method of claim 1, wherein the data further identifies an equipment manufacturer for each equipment component, and wherein the training need is identified for equipment components from a particular equipment manufacturer.

14. The method of claim 1, wherein the data further includes data representative of downtime for the equipment components, and wherein the parameter includes downtime.

15. A system for identifying training needs associated with a plurality biomedical equipment components in a medical institution, the system comprising:

a central database configured to store data representative of the equipment components, the stored data including operation data and identification data identifying at least an equipment type;

a data analysis module configured to arrange the operation data into logical groupings and to analyze the operation data based on the logical groupings, the logical groupings including an equipment type grouping; and

a report generator configured to generate a report including an arrangement of the analyzed operation data based on the logical groupings, wherein a training need is identifiable based on the arrangement.

16. The system of claim 15, wherein the operation data includes breakdowns associated with the equipment components, and wherein the arrangement of the analyzed operation data comprises a presentation of the breakdowns associated with a particular equipment type.

17. The system of claim 15, wherein the operation data includes operator errors associated with the equipment components, and wherein the arrangement of the analyzed operation data comprises a presentation of the operator errors associated with a particular equipment type.

18. The system of claim 15, wherein the arrangement of the operation data includes a first presentation of the operation data for a particular medical facility and a second presentation of the operation data for a plurality of medical facilities.

19. The system of claim 18, wherein the medical facilities are at geographically diverse locations.

20. The system of claim 18, further comprising a user interface configured to provide access to the generated report.

21. The system of claim 20, wherein the report is generated at a location remote from the medical institution and is transmitted to the medical institution via a communication network.

22. The system of claim 21, wherein the communication network includes the Internet.

23. A method for identifying a training need associated with biomedical equipment in a medical institution, the method comprising:

storing data associated with the equipment in a central database, the stored data including equipment operation data and equipment identification data;

logically grouping the stored equipment operation data in accordance with the corresponding equipment identification data;

analyzing the equipment operation data based on the logical grouping;

generating a presentation of the analyzed equipment operation data in accordance with the logical grouping; and

identifying a training need associated with a particular piece of equipment based on the presentation.

24. The method of claim 23, wherein the logical grouping comprises an equipment type grouping, an equipment manufacturer grouping, and an equipment location grouping.

25. The method of claim 24, wherein the equipment location grouping comprises locations of the pieces of equipment.

26. The method of claim 24, wherein the location grouping references a plurality of geographically diverse medical facilities.

27. The method of claim 23, wherein the operation data includes breakdowns and operator errors associated with the equipment.

28. A system for identifying training needs for biomedical equipment in a medical facility, the method comprising:

means for collecting identification and operation data associated with a plurality of biomedical equipment components;

means for storing the collected data in a central database;

means for analyzing the operation data to identify at least one operational parameter affected by operator activities with the equipment components; and

means for identifying a training need based on the analyzed operational parameter.